

Claims 1, 14, 23-25, and 30-31 are amended herein. The amendments are supported fully by the claims and/or specification as originally filed and, thus, do not represent new subject matter. In particular, the amendments to Claim 1 are supported at page 16, middle paragraph, page 38, final paragraph, and at page 15, final paragraph, of the specification as filed. Amendments to Claims 23-25 are made in response to Examiner's suggestion. Amendments to Claims 14 and 30-31 are made to comply with Examiner's request for improved clarity.

Applicants respectfully request entry of the amendments and remarks made herein into the file history of the present invention. Reconsideration and withdrawal of the rejections set forth in the above-identified Office Action are respectfully requested.

**I. The Rejection Under 35 U.S.C. § 102(b) Should Be Withdrawn**

The Office Action, at pages 3-4, paragraph 7, rejects claims 1-7, 14, and 20-33 as allegedly being anticipated by U.S. Patent No. 5,783,269 to Heilmann (hereinafter, "Heilmann") under 35 U.S.C. § 102(b). The Office Action alleges that Heilmann anticipates the above-mentioned claims of the present invention based on the alleged disclosure by Heilmann of structurally identical multilayer films (*i.e.*, multilayer films having similar design characteristics in terms of the arrangement, number, and composition of the layers) having identical mechanical properties. Applicants traverse respectfully.

Applicants submit respectfully that the claims of the present invention, as amended, are not anticipated by Heilmann. Without acquiescing in the propriety of the arguments made in the Office Action with respect to the identity of structure of the multilayer films of Heilmann compared with those of the present invention (*i.e.*, multilayer films having similar design characteristics in terms of the arrangement, number, and composition of the layers), Applicants asserts respectfully that the mechanical properties of the films according to

Heilmann are not identical with those of the films of the present invention and, in fact, the mechanical properties of films of the present invention are vastly superior to those of Heilmann. As noted in the Office Action in the last line of page 3 to the first two lines of page 4, the mechanical strength of films according to Heilmann is measured by the "drop test" method (see Heilmann, column 8, lines 20-22) whereby bags made from the film and filled with fluid are dropped from various heights to test for mechanical failure under those conditions. Applicants submit respectfully that the Office Action equates the drop test with tests that measure film yield, such as those according to DIN ISO 527-1 to -3. Applicants submit respectfully that the drop test, although it is a standard test of film strength and durability, is *not* a measure of film yield (*i.e.*, the amount of length the film will stretch under a given load). While Heilmann discloses films that are resistant to breakage under the drop test, Heilmann does not recite films that have no measurable yield. In fact, Applicants submit respectfully that Heilmann teaches films that *do* yield. For example, Heilmann, at column 8, lines 41-43, recites that the "film is slightly biaxially oriented during the production process at a stretching ratio of: longitudinal stretching/transverse stretching = 2.3/1.4." Applicants submit respectfully that the claims of the present invention, as amended, are quite explicit in requiring that films of the present invention have *no measurable yield*, whereas the films of the prior art, *e.g.*, Heilmann, do have a measurable yield.

Respectfully, Applicants draws the Examiner's attention to Table 3, at pages 36 to 37 of the specification as filed, which recites a comparison of the results of traction-elongation tests (according to DIN ISO 527-1 to -3) made on films manufactured according to the specifications of the prior art (labeled "Comp. Ex."), including Heilmann, with films made according to methods of the present invention (labeled "Example"). Applicants submit respectfully that the films according to the prior art indeed have measurable yield in this test, whereas films according to the present invention have no measurable yield. The only

exception is comparative example 1 (Comp.Ex. 1). However, the film of comparative example 1 requires an outer layer made of a polyester (PET1) which is a serious drawback, as is discussed in the present application's specification at page 2, and falls outside the scope of the present claims. Applicants submit respectfully that the present invention, for the first time, provides films consisting of 100% polyolefin materials, optionally with low amounts of rubber materials, that avoid the use of PVC and PET while retaining the advantageous mechanical properties of films of the prior art that include these materials.

Applicants submit respectfully that it is shown herein that Heilmann does not anticipate the claims of the present invention. As the Examiner is no doubt well aware, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Applicants submit respectfully that the claimed element of "no measurable yield" is set forth neither explicitly nor inherently in Heilmann. Accordingly, Applicants requests respectfully that the rejection of Claims 1-7, 14, and 20-33 under 35 U.S.C. § 102(b) be withdrawn.

## **II. The Rejections Under 35 U.S.C. § 103(a) Should Be Withdrawn**

### **A. Rejections over Heilmann**

The Office Action, at pages 5-6, paragraphs 9 and 10, rejects Claims 8-9, 18-19, and 20-22 as allegedly being obvious over Heilmann, under 35 U.S.C. § 103(a). The Office Action alleges that one of ordinary skill in the art would be able to readily determine appropriate ranges of thickness, melting points, and VICAT temperatures to reach a desired end use through routine optimization. Applicants traverse respectfully.

As a threshold issue, Applicants submit respectfully that since, as noted above, Heilmann fails to teach, suggest, or disclose a multilayer film having no measurable yield, it

is impermissible to consider obviousness of obtaining appropriate ranges of thickness, melting points, and VICAT temperatures to reach a desired end use through routine optimization.

Further, Applicants submit respectfully that Heilmann teaches away from determination of appropriate ranges by routine optimization. At column 6, lines 33-45, Heilmann discusses the complexities of manufacturing complex multilayer films. In particular, Applicants respectfully draws Examiner's attention to lines 34-37, in which Heilmann recites, "it was not predictable on the basis of past experience that such a complex multi-layer film of the type according to the invention could straightforwardly be achieved with success. Heilmann recites that success in this field is "surprising" and that "practical experience has repeatedly shown that, even with the assistance of sometimes tabulated polymer properties, such as composite adhesion data, the use of such materials does not lead to success." Finally, at column 6, lines 42-45, Heilmann recites that, "in other words, solving a particular problem in a mult-layer co-extruded film by simply making a selection from known materials is not in principle straightforwardly possible."

Applicants submit respectfully that it is well known in patent law that no finding of obviousness may be made over a reference that teaches away from construction of the present invention. In an obviousness inquiry, the relevant question is whether the prior art suggests the invention and whether the prior art provides one of ordinary skill in the art with a reasonable expectation of success. *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673 (Fed. Cir. 1988). Both the suggestion and the reasonable expectation of success must be founded in the prior art and not in the Applicants's disclosure. *In re Vacek*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (emphasis added). Applicants submit respectfully that the claimed invention is not obvious over Heilmann, because Heilmann does not teach, suggest or provide the requisite expectation of success for determination of appropriate ranges of thickness,

melting points, and VICAT temperatures to reach a desired end use through routine optimization. In fact, as noted above, Applicants submit respectfully that Heilmann actually teaches away from such routine optimization. Accordingly, Applicants requests respectfully that the rejections of Claims 8-9, 18-19, and 20-22 under 35 U.S.C. § 103(a) be withdrawn.

**B. Rejections Over Heilmann In Light Of U.S. Patent No. 5,686,527 To Laurin *et al.* And U.S. Patent No. 6,348,568 To Barney *et al.***

The Office Action, at page 7, paragraph 11; rejects Claims 10-13, and 15-17 as allegedly being obvious over Heilmann in light of U.S. Patent No. 5,686,527 to Laurin *et al.* (hereinafter, "Laurin"), under 35 U.S.C. § 103(a). The Office Action alleges that Laurin cures a deficiency in Heilmann wherein Heilmann does not disclose films having a modulus of elasticity of less than 100 MPa for an inner layer and at least 400 MPa for an outer layer, as recited in the present claims. While admitting that Laurin does not disclose films having the recited moduli of elasticity (*i.e.*, Laurin discloses films having a modulus of elasticity in the range of 150-300 MPa), the Office Action alleges further that it would be obvious to one skilled in the art to vary the modulus of elasticity through routine optimization to obtain a desired result. At page 8, paragraph 12, the Office Action rejects Claim 34 of the present invention under 35 U.S.C. § 103(a) as allegedly being obvious over Heilmann in light of U.S. Patent No. 6,348,568 to Barney *et al.* (hereinafter, "Barney"). The Office Action alleges that Barney cures a deficiency in Heilmann whereby Heilmann fails to disclose packaging which stores fluid lipophilic emulsions. Applicants traverse respectfully.

As a threshold issue, Applicants submit respectfully that since, as noted above, Heilmann fails to teach, suggest, or disclose a multilayer film having no measurable yield and, since the Office Action does not assert that Laurin or Barney cures this deficiency, it is impermissible to consider obviousness of varying the modulus of elasticity through routine

optimization to obtain a desired result or to consider packaging which stores fluid lipophilic emulsions.

Further, Applicants submit respectfully that Heilmann, either alone or in combination with Laurin or Barney, fails to show the necessary teaching, suggestion, or motivation, required to prove a *prima facie* case of obviousness. "It is impermissible to reconstruct the claimed invention from selected pieces of prior art absent some suggestion, teaching, or motivation in the prior art to do so." *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1051-2, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988). Absent some teaching, suggestion, or motivation found within Heilmann, Laurin, or Barney that the modulus of elasticity and/or storage of lipophilic solutions claimed by Applicants are desirable, it cannot be inferred that Applicants's invention would have been obvious to one of ordinary skill in the art. "It is insufficient to select from the prior art the separate components of the inventor's combination, using the blueprint supplied by the inventor." *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ2d 543, 551 (Fed. Cir. 1985).

Applicants submit respectfully that Heilmann does not teach, suggest, or motivate one skilled in the art to combine the teachings of Laurin or Barney with Heilmann in order to reach the present invention. Moreover, in the case of Laurin, Applicants submit respectfully that Heilmann actually teaches away from the likelihood of achieving success through routine optimization. In light of these facts and the case law noted above, Applicants submit respectfully that the Office Action has failed to meet the burden necessary for combining Laurin and Barney with Heilmann to reach the present invention. Even further, if Laurin and Barney are combined with Heilmann, Applicants submit respectfully that the Office Action still fails in its burden of obviousness for lack of disclosure of films having no measurable yield. Accordingly, Applicants requests respectfully that the rejections to Claims 10-13, 15-17, and 34 under 35 U.S.C. § 103(a) be withdrawn.

### III. Rejections Under 35 U.S.C. § 112, Second Paragraph

At page 2, paragraph 2, of the Office Action, Claim 1 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to point out particularly and claim distinctly the subject matter regarded as the invention. The Office Action alleges that the claim is unclear because the phrase "hot water steam spraying process" is indefinite, and that the phrase "the film displays no measurable" is indefinite. Applicants traverse respectfully.

Applicants asserts respectfully that Claim 1, as amended, is not indefinite. Claim 1 as filed contained translation errors from the original German and an inadvertent omission, both corrected herein. The German Claim 1 originally comprised the term "nach einer Heißdampfsterilisierung bei 121 °C oder höheren Temperaturen" im Heißwasserberieselungsverfahren." This was translated originally to read "following hot sterilization at 121 °C or higher temperatures using a hot water steam spraying process." However, a more correct translation of the original German version reads, "following hot *steam* sterilization at 121 °C or higher temperatures using a *hot water spraying process*" (emphasis added). Claim 1 is amended herein to so recite. Further, the original claim recited, "the multilayer film displays no measurable yield *according to DIN EN ISO 527-1 to -3*" (emphasis added). Claim 1 is amended herein to so recite.

As is recited at page 16, middle paragraph, and at page 38, final paragraph, of the specification as filed, the films according to the invention are subjected to a sterilization treatment with heated steam at 121 °C. The specific term for this treatment is known to the person skilled in the art as "hot (or heated) water spray(ing) process." As is well known in the art, a hot water spraying process is a process for the sterilization of goods, wherein the sterilization water which is used as a heat carrier for heating the articles (goods) to be

sterilized is carried in a closed circuit. By the addition of pressurized air, the pressure in the sterilization chamber can be changed. Hence, Applicants submit respectfully that Claim 1, as amended, is definite and clear as to the meaning of the expression, "hot water spraying process."

As recited at page 15, last paragraph, the hot steam sterilized films of the present invention are characterized in that they do not exhibit a measurable yield according to DIN EN ISO 527-1 to -3. All of the yield values determined in connection with multilayer films of the present invention have been determined with films that have been heat sterilized with hot steam at temperatures of at least 121 °C over a time sufficient for the practical use of the sterilized bags that have been obtained from the films under consideration. Without acquiescing as to the allegation that the term "measurable" *per se* may be indefinite, Applicants submit respectfully that in Claim 1, as amended, the method to be used for determining the presence or absence of a measurable yield is clear and concise. Applicants submit respectfully that, in particular, DIN EN ISO 527-1 to -3 provides a clear definition of the tests by which yield is measured, and renders Claim 1 clear and precise when combined with the respective statements in the description.

Accordingly, Applicants submit respectfully that the rejections have been traversed, and Applicants request respectfully that the 35 U.S.C. § 112, second paragraph, rejection of Claim 1 be withdrawn.

At page 2, paragraph 3, of the Office Action, Claim 14 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to point out particularly and claim distinctly the subject matter regarded as the invention. The Office Action alleges that the claim is indefinite because the phrase "the middle layer has a yield" contradicts the recitation of Claim 1, which recites, "no measurable yield." Applicants traverse respectfully.



Without acquiescing in the propriety of the Office Action's allegation, and solely to further prosecution of the present application, Applicants amends Claim 14 to recite, "has a measurable yield of less than or equal to 8 Mpa *when measured separately*" (emphasis added) to improve the clarity of the claim language. Applicants submit respectfully that the text of Claim 14, as filed, does not contradict the recitation of Claim 1 because Claim 14 recites only that the *middle layer* shows a slight measurable yield. Claim 14 does not recite that the combined, multilayer film would have a measurable yield, and Applicants submit respectfully that it is certainly conceivable that one layer of a multilayer composite might be stretchable where a second layer is not, the second layer thus providing the composite with an unyielding quality, overall. Accordingly, Applicants suggests respectfully that the rejection has been traversed, and Applicants requests respectfully that the 35 U.S.C. § 112, second paragraph, rejection of Claim 14 be withdrawn.

Paragraph 4 of the Office Action, at pages 2-3, rejects dependent Claims 23-25 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to point out particularly and claim distinctly the subject matter regarded as the invention. The Office Action alleges that the claims are indefinite because the transitional term "comprises" is indefinite in relation to the recitation of the phrase "consists of" in the parent Claim 1. Applicants traverse respectfully.

Without acquiescing in the propriety of the allegations in the Office Action, and solely to further prosecution of the present application, Applicants herein amend Claims 23-25 to recite "consists of" in place of the term "comprising" in those claims. Accordingly, Applicants suggests respectfully that the rejection has been traversed, and Applicants requests respectfully that the 35 U.S.C. § 112, second paragraph, rejection of Claims 23-25 be withdrawn.

Paragraph 5 of the Office Action, at page 3, rejects Claims 30-31 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to point out particularly and claim distinctly the subject matter regarded as the invention. The Office Action alleges that the claims are indefinite because the meanings of the phrases “lining the layers” and “lined as a flat film” are unclear. Applicants traverse respectfully.

Without acquiescing in the propriety of the allegations in the Office Action, and solely to further prosecution of the present application, Claims 30-31 are amended herein to correct vagaries in translation. The phrases “lining the layers” and “lined as a flat film” in the claims are a confusing translation of the original German. The German term “kaschieren” is used for multilayer films consisting of different layers that are bonded together by the use of temperature and pressure and/or an adhesive. The typical result of “kaschieren” is a laminate. Applicants submit respectfully that the term “lining” is not intended to express an orientation of the layers of films of the present invention but, rather, to cover the general concept of connecting or bonding the film layers. In other words, “lining” is not meant to imply “lining up” or “aligning,” but is meant, rather, to convey “lining” in the sense of the lining of one substance *with* another, as a leather glove may be lined with fur, or the inner surface of a television picture tube is lined with phosphorescent dots. Therefore, to improve clarity, Claims 30-31 are amended herein to indicate that the layers are joined, or bonded, together. In support of this analysis, Applicants respectfully turn Examiner’s attention to page 33 of the specification, as filed, wherein non-limiting examples of manufacturing processes are described. Applicants submit respectfully that, as one skilled in the art would readily appreciate, manufacture of a multilayer film according to the recited process of extrusion and pouring of molten polypropylene sheets one on top of another onto a sheet die results, in at least cases wherein the individual sheets are not cooled to a fully cured condition by the water cooled roller, in bonding of the individual sheets together on the die as they cool and cure.

Accordingly, Applicants suggests respectfully that the rejection has been traversed, and Applicants requests respectfully that the 35 U.S.C. § 112, second paragraph, rejection of Claims 30-31 be withdrawn.

### **CONCLUSION**

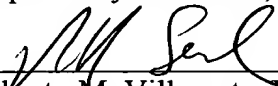
Applicants submit that the application is in condition for allowance. Favorable reconsideration, withdrawal of the rejections set forth in the above-noted Office Action, and an early Notice of Allowance are requested.

Applicants' undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should be directed to our address given below.

### **AUTHORIZATION**

Applicantss believe there is no fee due in connection with this filing. However, to the extent required, the Commissioner is hereby authorized to charge any fees due in connection with this filing to Deposit Account 50-1710 or credit any overpayment to same.

Respectfully submitted,

  
\_\_\_\_\_  
Gilberto M. Villacorta, PH.D.  
Registration No. 34,038  
Robert R. Seabold, PH.D.  
Registration No. 41,298

Patent Administrator  
KATTEN MUCHIN ZAVIS ROSENMAN  
525 West Monroe Street, Suite 1600  
Chicago, Illinois 60661-3693  
Facsimile: (312) 902-1061

Dated: November 5, 2002

**EXHIBIT A**

**MARKED-UP VERSION OF THE CLAIMS  
U.S. PATENT APPLICATION NO. 09/733,079**

1. (Once amended) A multi-layer film comprising at least three layers, an outer layer (A), an inner layer (I) and, disposed in between, a middle layer (M), each of which consists of up to 60 to 100% by weight of polypropylene materials and up to 40 to 0% by weight of a thermoplastic elastomer, respectively referring to the total weight of the respective layer, wherein following hot steam sterilization at 121°C or higher temperatures using a hot water [steam] spraying process, the multi-layer film displays no measurable yield according to DIN EN ISO 527-1 to -3.

14. (Once amended) The multi-layer film according to claim 1, wherein the material of the middle layer (M) has a measureable yield of less than or equal to 8 Mpa when measured separately.

23. (Once amended) The multi-layer film according to claim 1, wherein the layers (A), (M) consist of [comprise] up to 100 % by weight and the layer (I) by up to 60 to 100 % by weight, of one or more polymers selected from the group consisting of homopolymers of polypropylene (homo-PP's), random copolymers of polypropylene (random co-PP's), block copolymers of polypropylene, flexible copolymers of polypropylene (co-FPO's), flexible copolymers of polypropylene (co-FPO's), and the layer (A) consists of [comprises] additionally up to 40 to 0% by weight styrene-ethylene/butylene-styrene block copolymers (SEBS).

24. (Once amended) The multi-layer film according to claim 23, wherein the layer (I) consists of [comprises] up to 70 to 90% by weight of one or more polymers from the group consisting of homopolymers of polypropylene (homo-PP's), random copolymers of polypropylene (random co-PP's), block copolymers of polypropylene, flexible copolymers of polypropylene (co-FPO's), flexible copolymers of polypropylene (co-FPO's).

25. (Once amended) The multi-layer film according to claim 23, wherein the layer (A) consists of [comprises] additionally up to 30 to 10% by weight of styrene-ethylene/butylene-styrene block copolymers (SEBS).

30. (Once amended) A method of producing a multi-layer film according to claim 1, comprising joining [lining] the layers with one another.

31. (Once amended) The method according to claim 30, wherein the film is joined [lined] as a flat film.